USAMRMC CONTROL NUMBER:
DEPARTMENT OF THE ARMY CONROL NUMBER:

U. S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
BIOLOGICAL MATERIALS LICENSE AGREEMENT

This **Agreement** is entered into between the ***[USAMRMC Laboratory Name]*** (hereinafter ***Laboratory Name;*** **Licensor**") a subordinate Laboratory of United States Army Medical Research and Materiel Command (**"USAMRMC"**), located at ***[Street or location address]*** and ***[Company Name]***, (hereinafter ***[Company Name];*** **Licensee**"), ***[Corporate type]*** located at ***[Address]***.

Under the authority of 15 United States Code 3701 et seq., 35 United States Code Sections 200 - 210, and 37 Code of Federal Regulations, Chapter IV (together with any amendments and the underlying rules and regulations now or hereafter promulgated collectively, the "***Federal Technology Transfer Act***" or the "***FTTA***"), ***[Laboratory Name]*** has the authority to enter into this Biological Material License Agreement.

BACKGROUND: ***[A description of the product and the use to which company will apply it; any reference to MRMC patent docket #/invention disclosure #; keep information in this section general]***

1. Definitions:

(a) "**Materials and/or Methods**" means the following biological material including all related information/descriptions ***[including clones, subclones, progeny, derivatives, composition, and know-how]***.

(b) "**Licensed Products**" means ***[describe the product]identify product].***

(c) **"Licensed Field of Use** " means ***[describe the use].***
.

(d**)** **"Net Sales*"*** means the actual gross amount billed, invoiced, charged or received on sales or transfers of any **Licensed Products** by **Licensee**, its Affiliates to any and all Unaffiliated Person(s), or in the event of disposal of any **Licensed Products** other than as scrap prior to shipment from its place of manufacture or predisposal storage, or other than by sales, the amount billed, invoiced, charged or received on sales or transfers for a like quantity and quality of **Licensed Products** to Unaffiliated Persons on or about the time of such disposal, less:

(i) trade, cash and quantity discounts, including charge backs, rebates, premiums, allowances and any other deduction actually granted to the Unaffiliated Person (not to exceed the original billing);

(ii) sales and excise taxes and duties and any other governmental charges imposed upon the importation, use or sale of the **Licensed Products** actually charged to the Unaffiliated Person;

(iii) freight, insurance and other transportation charges actually charged to the Unaffiliated Person; and

(iv) amounts repaid or credited (not to exceed the original billing) by reason of rejections, defects, outdating, price differences, recalls or returns, or because of retroactive price reductions, or due to governmental laws or regulations requiring rebates actually granted to the Unaffiliated Person.

The cumulative total of deductions specified above shall not decrease **Net Sales** by more than one-third compared to **Net Sales** calculated without consideration of these deductions.

For purposes of calculating **Net Sales** for any reporting period, any and all deductions used in calculating **Net Sales** are allowable only to the extent that they have already been included in the amounts billed, invoiced, charged or received or granted on the sales or transfers of **Licensed Products** by Licensee or its Affiliates to Unaffiliated Persons in bona fide arms' length transactions. Calculation of **Net Sales** shall be in accordance with generally accepted accounting principles. Sales or transfers of **Licensed Products** between or among **Licensee** and its Affiliate(s) shall be excluded from the computation of **Net Sales** except where such Affiliate(s) are End Users, but **Net Sales** shall include the subsequent final sales or transfers to Unaffiliated Persons by such Affiliate(s) (if not End Users).

2. **Licensee** desires to obtain a license from **Licensor** to use the **Materials and/or Methods** provided under this **Agreement** in its commercial research or product development and marketing activities. **Licensee** represents that it has the facilities, personnel, and expertise to use the **Materials and/or Methods** or the **Licensed Products** for commercial purposes and agrees to expend reasonable efforts and resources to develop the **Materials and/or Methods** or the **Licensed Products** for commercial use or commercial research.

3. **Licensor** hereby grants to **Licensee**:

(a) a **[worldwide]**, **[non-exclusive/exclusive]** license to make, have made, and use the **Materials and/or Methods** or the **Licensed Products**; and

(b) a **[worldwide]**, [**non-exclusive/exclusive**] license to sell and have sold, to offer to sell and to import the **Licensed Products** in the **Field(s) of Use**.

4. In consideration of the grant in Paragraph 3, **Licensee** hereby agrees to make the following payments to **Licensor** according to the following schedule:

(a) An initial execution fee is due within Forty-five (45) days of upon execution. The terms of the License **Agreement** are as follows:

(i) A one-time execution fee of ***[$ x]*****.**

(ii) **Licensee** shall pay **Licensor** an annual royalty of ***[X.X]*** % of **Net Sales** for the Materials **and/or Methods** Used in ***[Licensed Products]***.

(iii) A nonrefundable minimum annual payment of [***X dollars]*** to be credited against the annual **Net Sales** royalty *due on* ***Licensed Products.***.

(iv) From and after the date of initiation throughout the term, **Licensee** shall make a one time payment of [***X dollars]*** upon achieving **[$xx]** in accumulated worldwide sales of the

LICENSED PRODUCTS.

(v) From and after the date of initiation throughout the term, Licensee shall make a one time payment of X dollars upon successful completion and compliance/approval of ***any regulatory milestone of U.S. Food and Drug Administration (FDA) or any other regulatory Agency as herein detailed: 1, 2, 3 etc]***.

(vi) Licensee will reimburse Licensor **[$x] for past costs and/or will pay [*y%]* of all future]** patent prosecution Costs, *if a patent exists*.

(b) All royalties shall be due and payable within forty five (45) days of the end of each calendar year.

(c) All payments required under this **Agreement** shall be paid in U.S. dollars. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due.

(d) Licensor will notify **Licensee** in written and/or electronic communication of Department of the Army and USAMRMC control numbers. **Checks must be made payable to** "**DFAS ROCK ISLAND**." On a statement accompanying the check, it shall be noted that the payment is for royalties or licensing fees, and United States Department of Army log number(s) **MUST** be listed and specifically referenced. In the case where payments of License Fees are made on more than one licensed patent, patent application, invention, technology or **Licensed Product, Licensee** shall submit an estimated allocation of payments amongst the relevant licensed patents, patent applications, inventions, technologies or **Licensed Products**. All checks for payments under this **Agreement** should be mailed to the below address with a copy to **Licensor's** representative at the address on the signature page.

(e) Address to send payments:

DFAS
ROCK ISLAND OPLOC
ATTN: DFAS-RI-FD
Building 68, Rock Island, IL 61299-8300

(f) Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee.**

(g) Additional royalties may be assessed by **Licensor** on any payment that is overdue at the rate of twelve percent (12%) per annum. This twelve percent (12%) per annum rate may be applied retroactively from the original due date until the date of receipt by **Licensor** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **Licensor** from exercising any other rights it may have as a consequence of the lateness of any payment.

5. Upon receipt and verification by **Licensor** of the execution fee and/or other payments agreed to by the parties, **Licensor** agrees to provide **Licensee** with the **Materials and/or Methods**, as available, and to replace these **Materials and/or Methods**, as available, at reasonable cost, in the event of their unintentional destruction.

6. **Licensee** agrees to make written reports to **Licensor** within forty-five (45) days of December 31st and June 30th for each calendar year. This report shall state: the number, description, and aggregate **Net Sales** of **Licensed Products** made, sold, or otherwise disposed of; the total gross income received by **Licensee** from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other disposition transferring title, during the calendar year; and the resulting calculation of earned royalties due **Licensor. Licensee** shall submit each report to **Licensor** at the Mailing Address for **Agreement** notices indicated on the Signature Page.

7. This **Agreement** shall become effective on the date when the last party to sign has executed this **Agreement** and shall expire **[x]** years from this effective date, unless previously terminated under one of the other terms of this Agreement. **[Use patent terminology if patented i.e. life of patent etc.]**

8. As part of **Licensee's** performance under this **Agreement**, **Licensee** agrees to make the **Licensed Products** available to the public within ***[x number of months-negotiated]***.

9. **Licensee** agrees to retain control over the **Materials and/or Methods** and the **Licensed Products**, and not to distribute them to third parties without the prior written consent of **Licensor** except as provided in Paragraph 3.

10. This **Agreement** does not preclude **Licensor** from distributing the **Materials and/or Methods** or the **Licensed Products** to third parties for research or commercial purposes.

11. By this **Agreement**, **Licensor** grants no patent rights expressly or by implication to any anticipated or pending **Licensor** patent applications or issued patents.

12. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE **MATERIALS AND/ OR METHODS** PROVIDED TO **LICENSEE** UNDER THIS **AGREEMENT**, OR THAT THE **MATERIALS** AND/ OR METHODS OR THE **LICENSED PRODUCTS** MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. **LICENSEE** ACCEPTS LICENSE RIGHTS TO THE **MATERIALS AND/OR METHODS** AND THE **LICENSED PRODUCTS** "AS IS", AND **LICENSOR** DOES NOT OFFER ANY GUARANTEE OF ANY KIND.

13. **Licensee** agrees to indemnify and hold harmless the United States Government from any claims, costs, damages, or losses that may arise from or through **Licensee's** use of the **Materials and/or Methods** or the **Licensed Products**. **Licensee** further agrees that it shall not by its action bring the United States Government into any lawsuit involving the **Materials and/or Methods** or the **Licensed Products**.

14. **Licensee** agrees in its use of the supplied **Materials and/or Methods** or the **Licensed Products** to comply with all applicable statutes, regulations, and guidelines. **Licensee** agrees not to use the **Materials and/or Methods** or the **Licensed Products and/or Methods** for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46 and approval by **Licensor**.

15. **Licensee** may terminate this **Agreement** upon sixty (60) days written notice to **Licensor, Licensor** may terminate this **Agreement** if **Licensee** is in default in the performance of any material obligation under this **Agreement**, and if the default has not been remedied within ninety (90) days after the date of written notice by **Licensor** of the default.

16. Upon termination or expiration of this **Agreement**, **Licensee** agrees to return all **Materials and/or Methods** and the **Licensed Products** to **Licensor**, or provide **Licensor** with written certification of their destruction.

17. Within sixty (60) days of termination or expiration of this **Agreement**, **Licensee** agrees to submit a final report to **Licensor**, and to submit to **Licensor** payment of any royalties due.

18. **Licensee** agrees to keep records showing the gross sales, **Net Sales** or other disposition of **Licensed Products** sold or otherwise disposed of under the license appropriate to determine the amount of fees and other payments due USAMRMC hereunder. Such records, including, without limitation, those of its Affiliates and Sublicensees, shall be retained for a period of five (5) years following the end of the calendar year to which such records pertain, and shall be treated and maintained as Confidential Information of Licensee. Such records should be in sufficient detail and clearly organized to enable the fees and any other amounts payable hereunder by **Licensee** to be determined, and **Licensee** further agrees to afford **USAMRMC** or its designee(s) or agent(s) access to examine any and all relevant books and records of **Licensee** and, where appropriate, its Affiliate(s) and Sublicensees, as may be necessary to make such determination. Upon thirty (30) days prior written notice, **Licensee** shall make such records available for examination during normal business hours for the sole purpose of verifying the accuracy of **License**e's payments and compliance with this Agreement for any period within the most recently completed five (5) calendar years during the term of this Agreement and for five (5) years after the expiration or termination of this Agreement. If an auditor or certified public accountant is appointed by USAMRMC to conduct such an examination, USAMRMC shall, at **Licensee**'s sole cost and expense, review and approve any reasonable request that its designee or agent execute an agreement not to otherwise disclose confidential or proprietary information. **Licensee** shall also assume and pay any and all audit expenses and costs incurred in the event any underpayment is reported which equals or exceeds 5% of the License Fees or other payments due USAMRMC hereunder. The parties agree to adhere to the rules and procedures established under the Administrative Dispute Resolution Act (5 USC Section 571, as amended) to resolve any dispute arising under this Section.

19. **Licensee** is encouraged to publish the results of its research projects using the **Materials and/or Methods** or the **Licensed Products**. In all oral presentations or written publications concerning the **Materials and/or Methods** or the **Licensed Products**, **Licensee** shall acknowledge the contributions of **Licensor** the agency supplying the **Materials and/or Methods**, unless requested otherwise by **Licensor**.

20. This **Agreement** shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. **Licensee** agrees to be subject to the jurisdiction of U.S. courts.

21. This **Agreement** constitutes the entire understanding of **Licensor** and **Licensee** and supersedes all prior agreements and understandings with respect to the **Materials and/or Methods** or the **Licensed Products**.

22. The provisions of this **Agreement** are severable, and in the event that any provision of the **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, the invalidity or unenforceability of any provision of this **Agreement**, shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

23. Paragraph 12, 13, and 20 of this **Agreement** shall survive termination or expiration of this **Agreement**.

SIGNATURES BEGIN ON NEXT PAGE

BIOLOGICAL MATERIALS LICENSE AGREEMENT

SIGNATURE PAGE

In Witness Whereof, the parties have executed this **Agreement** on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For ***[Laboratory Name]***:

_____ Date:_____
Director Name

Printed Name:_____

Title:_____

Mailing Address of Licensor's Representative for all **Notices** and **Copies of payments sent to DFAS**:

Office of Research and Technology Applications
Staff Judge Advocate (MCMR-ZA-J)
504 Scott Street
Fort Detrick, MD 21702-5012

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):

For: ***[Company Name]***

_____ Date:_____
Signature of Authorized Official

Title _____

Mailing Address:

_____

_____

_____

Any false or misleading statements made, presented, or submitted to the **United States Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).